Exactech® Optetrak® Total Knee System
Line Extension - Offset Tibial Tray
Special 510(k)

Summary of Safety and Effectiveness

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Device Information:

INTENDED USE

The Offset Tibial Tray components are intended to replace the patient's proximal tibia during primary or revision total knee arthroplasty. The Optetrak Offset Tibial Tray is intended for use when the tibial intramedullary (IM) canal is offset from the tibial plateau.

INDICATIONS

The OPTETRAK® Total Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

CONTRAINDICATIONS

The OPTETRAK® Total Knee Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, and in patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and in patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

CAUTION: In the USA, for cemented use only.

Device Modifications

The device modifications presented in this Special 510(k) represent changes to the Tibial Tray Components of the Optetrak Total Knee System (premarket notifications #K933610 and #K011976). No changes were made to the other components of the Optetrak Total Knee System.

The proposed device modifications involve offsetting the distal portion of the tray's stem in the sizes 0, 1 Delta, 1, 2, 3, 4 and 5. This is done in order to accommodate varying patient anatomies.

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No modifications have been made to the mating features of the Tibial Tray in order to maintain the full mating capabilities with all tibial inserts, augmentation components and stem extensions of the predicate Optetrak Total Knee System

The proposed offset design incorporates modified screws for attachment of the Constrained Condylar Tibial Inserts and the Tibial Stem Extensions.

There have been no changes to the material of the predicate Optetrak Tibial Tray components. Like the predicate Optetrak Tibial Tray components (#K933610 & #K011976), the proposed tray components are manufactured from titanium alloy (Ti 6 Al 4V) conforming to ASTM F-136.

PERFORMANCE DATA SUMMARY

Functional testing was conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading.

We conclude that the Optetrak Offset Tibial components are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Mr. Martin Sprunck
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K023186
Trade/Device Name: OPTETRAK® Total Knee System Offset Tibial Tray
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 19, 2002
Received: September 24, 2002

Dear Mr. Sprunck :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak® Total Knee System
Line Extension - Offset Tibial Tray
Special 510(k)

Indications for Use

510(k) Number: K023186

Device Name: Offset Tibial Tray

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CAUTION: In the USA, for cemented use only.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023186

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over the Counter Use No